

SUMMARY RESPONSE TO COMMENTS – MEMORANDUM OF UNDERSTANDING FOR THIRD-PARTY LABORATORY ASSESSORS

ELAP received eight public comments on the draft Memorandum of Understanding (MOU) for Third-Party Laboratory Assessors (TPAs). A summary of significant comments is below with staff response.

COMMENT SUMMARY	STAFF RESPONSE
<p>Assessor Qualifications – Four commenters expressed concern that TPA assessors may not be qualified to perform assessments and suggest ELAP evaluate their credentials on a case-by-case, per-assessment basis.</p>	<p>ELAP views verification of these qualifications on a case-by-case basis as duplicative and a waste of resources. Assessor qualifications are governed by a provider’s internal policies and procedures, which comply with the requirements of the TNI Standard, Volume 2: General Requirements for Accreditation Bodies Accrediting Environmental Laboratories (2016). The standard requires providers assign audits to assessors who are qualified to perform them.</p> <p>Thus, by default, the minimum requirement the TPAs must meet to enter into this agreement confirms that the assessors are qualified for the assessments they will perform. ELAP feels confident in this level of assurance. However, ELAP has implemented several formal processes to verify the qualifications at different times. These are described in the next comment summary (Oversight).</p>
<p>Oversight of TPA Activities – Four commenters suggest ELAP conduct an annual review of TPA activities using performance measures.</p>	<p>ELAP has several processes in place to audit TPA activities:</p> <ul style="list-style-type: none"> - Bi-annual review with each TPA of their work (this item is a requirement of the MOU) - ELAP’s annual internal audit - Complaint procedures for laboratories to file grievances <p>ELAP recognizes there will likely be questions during the implementation period, as this is an expansion of the use of TPAs in California and new to many laboratories. ELAP is committed to working collaboratively with the community and TPAs toward a sustainable and efficient process that is beneficial to all parties. To this end, the TPAs have agreed to meet with ELAP on a monthly basis following the effective date of the new regulations.</p>

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<p>Accreditation Authority – Three commenters requested ELAP add language to clarify that TPAs do not have accrediting authority for the purposes of California regulatory work.</p>	<p>Staff has added clarifying language.</p>
<p>Cost Control Measures – Two commenters suggest including a clause that would govern the TPA’s pricing of their services.</p>	<p>ELAP understands cost concerns for laboratories. However, prices for services are determined by the providers, who set them based on economic market conditions and competition with competitor firms, which creates incentive to provide services at the lowest possible cost to gain business. Additionally, providers are already prohibited from price gauging and price fixing by law. Staff declines to add language related to cost control measures.</p>
<p>DoD/DoE - Two commenters request clarification of why Department of Defense and Department of Energy-approved assessment agencies are included in the MOU, and no other federal agencies.</p>	<p>ELAP has determined on Department of Defense and Department of Energy require environmental laboratory assessor bodies to meet a standard at least as stringent as is required for recognition by the NELAC Institute. Should other federal agencies join these two in those requirements, ELAP would need to pursue amendment of its regulations, and respectively, this MOU. The determination was included in section 64802.20(c)(2) of the adopted regulations and does not necessitate any changes to the document.</p>
<p>Underground Regulation – One commenter alleges that the State Board does not have authority to require laboratories to directly pay the TPAs for services and that the MOU constitutes an underground regulation.</p>	<p>This comment questions the State Board’s authority to establish the requirement that the laboratories directly pay the third-party assessors for their assessments. The commenter asserts that if the legislature had wanted laboratories to directly pay the third party assessors, it would have stated that in section 100837, as it has in Health and Safety Code section 100870, which requires laboratories to “bear the cost” of participating in proficiency testing (PT) for obtaining accreditation and for their annual PT requirement.</p> <p>First, this issue was already decided by the State Board in its May 5th adoption of the regulations for ELAP, which included a requirement that “when an on-site assessment is performed by a third-party Assessment Agency contracted by ELAP to perform on-site assessments, a laboratory shall pay the third party Assessment Agency its market rate for the onsite assessment.” (64802.20((f).)</p>

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	<p>Secondly, the commenter is incorrect that this is inconsistent with the ELAA, and its comparison to the language in Health and Safety Code section 100870 is inappropriate. It is clear looking at the history of section 100837 that although it doesn't say anything about charging the laboratories for the third-party services – that is what was intended. That section was originally added as part of SB 1304 in 1999 – the idea of that bill was to make the state's program consistent with the federal NELAP program, allowing the state laboratories to be TNI accredited. That section required DPH to set regulations for use of "approved third party laboratory accreditation organizations" (TPLAOs). These are organizations that one could go to instead of the state agency for accreditation. Although it did not require the laboratories to pay the TPLAOs, it would not make sense for the money to be paid to ELAP instead of the third party. The law was changed in 2000, to allow for ELAP to "contract" with the third-party accreditation organizations in accordance with criteria developed by NELAC and federal agencies, instead of having to come up with its own regulations. The 5/12/2000 analysis done for that bill notes that the existing law allowed accreditation in one of three ways: 1) by DHS; 2) by TPLAOs under procedures and requirements set out in DHS regulations, or 3) accredited by DHS or another state under US EPA's NELAP – and proposed law would allow the TPLAOs to also meet TNI or federal requirements. In 2002, SB 2096 changed the language of "third party laboratory accreditation organization" to "third party assessor organizations" because TNI was modified to require the accreditation agencies to be states. Although third party assessors could be public or private entities, only states could accredit. So, as the history of these bills sets out, it would never have made sense for the laboratories not be able to pay the accreditation organizations directly. This is also what is done in other states that rely on TPAs.</p> <p>Additionally, using the language in section 100870 is not an appropriate comparison because that section needed to clarify when laboratories would be required to pay the cost of the proficiency tests versus when it was required to be paid for by the State Water Board because the statute covers a few different scenarios, and payment responsibility is different for each. In the situation where the laboratory is applying for accreditation or doing the annual PT sampling, it makes sense that the laboratory would have to pay for participation</p>

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	<p>in the PT study. The other situation described in the statute is more of a targeted enforcement situation, where the State Board goes into a laboratory and either provides a sample for analysis, or “indirectly” provides a sample for analysis. Here, the PT study does not need to come from a PT provider that meets TNI standards. It might be part of a special study with a university or part of an enforcement action. If the State Board identifies itself to the lab, the State Board doesn’t have to pay for the study; but if it does not identify itself – perhaps doing an undercover investigation – the statute clarifies that the laboratory does have to pay for the analyses.</p>